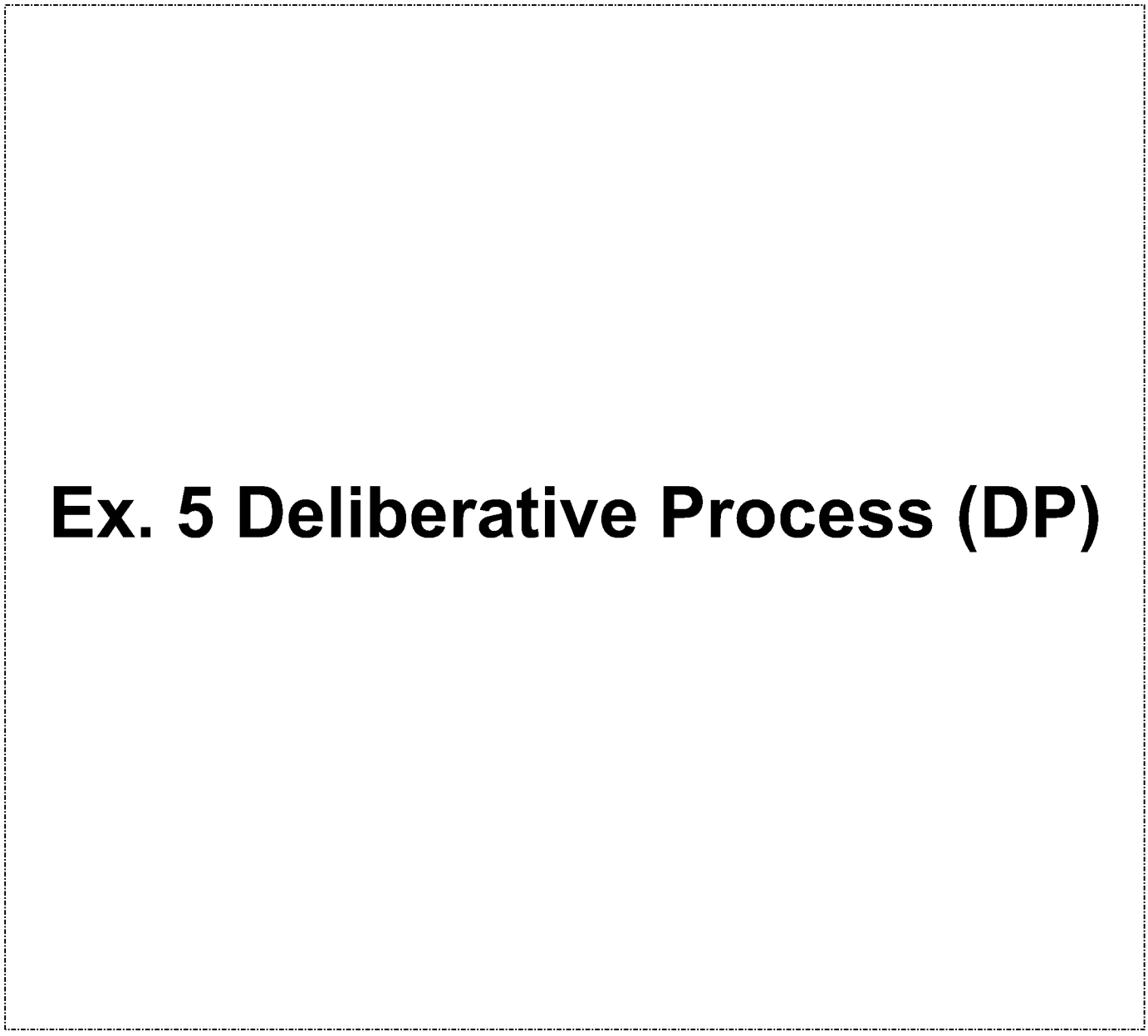
Message

From: Schaible, Stephen [Schaible.Stephen@epa.gov]
Sent: 11/3/2016 6:34:12 PM
To: Caulkins, Peter [Caulkins.Peter@epa.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Giles-Parker, Cynthia [Giles-Parker.Cynthia@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Holloman, Rachel [Holloman.Rachel@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Kenny, Daniel [Kenny.Dan@epa.gov]; Laws, Meredith [Laws.Meredith@epa.gov]; McCall, Deborah [McCall.Deborah@epa.gov]; Redden, John [Redden.John@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Shah, Pv [Shah.Pv@epa.gov]
CC: Roe, Lindsay [Roe.Lindsay@epa.gov]; Kish, Tony [Kish.Tony@epa.gov]
Subject: RD PRIA meeting minutes, 11/3/16

Thursday 11/3/2016

Agenda Items

1. SLITS:
2. ABN:
3. Deficiencies:
    1. FB (Lindsay, Tony)- Import tolerances for chlormequat chloride (first food use for this chemical) were petitioned. The technical screen closes 11/8/2016. The registrant came in with a waiver request for the acute neurotox (ACN) study. HASPOC already met on this submission. They said that the waiver was not granted but that they COULD put a 10x safety factor on in place of this guideline study but that it was not waived; it was required. RD is thinking that if this is a required study that they did not submit, then we should kick out the package for its incompleteness. However, the last time this registrant came in asking for this same waiver for their future section 3 first domestic food use, we sent them a letter (in 2016, so recently) saying – "the ACN will be required for the proposed first food use submission. In the absence of this ACN study, a 10x uncertainty factor will be applied for assessing acute, single dose exposure until the data need is satisfied." That's a little confusing. Is the package incomplete? Is this waiver determination something that we would generally consider as part of the technical screen? Should we send a 10-day letter.



4. Negotiated Due Dates:
    1. FHB (Rachel)- they are going to need to negotiate a due date b/c there is a risk issue due to DW modeling.
5. PRIA Topics:
    1. 

2. **Efficacy guidelines (Mark)**- bed bug guidelines is nearing completion in RD, almost ready to go around for comment (circle back with Pete)
    - When PRIA 4 does pass, keep the time frames and adjust the dates
3. **PPDC**- what is EPA going to do to streamline the big ticket items like new ai, first food uses.
    - Pete's answer: we are taking the 45/90d more seriously, kicking stuff out, using global/NAFTA- evaluating those processes and maybe scale back scope so we can make our dates

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